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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,979

02/10/2006

Kadem Ai-Lamee

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04/03/2008

Intellectual Property Dept.
Dewitt Ross & Stevens SC
2 East Mifflin Street
Suite 600
Madison, WI 53703-2865

EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,979	Applicant(s) AI-LAMEE ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, drawn to a composition comprising a polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol as well as a polymer of vinyl pyrrolidone and optionally vinyl acetate, along with a bioactive.

Group II, claims 10-14, drawn to method of applying a coating.

Group III, claims 15-20, drawn to a medical device.

Group IV, claim 21, drawn to method of using a medical device.

Group V, claims 15-20, drawn to a vehicle composed of a polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol as well as a polymer of vinyl pyrrolidone and optionally vinyl acetate.

The inventions listed as Groups I, II, III, IV, and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is a composition comprised of polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol as well as a polymer of vinyl pyrrolidone and optionally vinyl acetate. Ding (U.S. Patent No. 7,294,329) teach a coating composition for medical devices with a copolymer of a vinyl acetate, a vinyl acetal and a vinyl alcohol (see claims 1 and 10). Further, Ding also teaches the incorporation of a second

Art Unit: 1615

polymer into the composition (see claim 10). Eder et al. (U.S. PGPub No. 2002/0087184) teach that poly(vinyl pyrrolidone) was a known polymer used in coatings for medical devices (see paragraph 36 line 6). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use poly(vinyl pyrrolidone) as the second polymer in the coating composition of Ding, thereby making obvious the common technical feature of the instant invention. Thus since, the technical feature of the invention was known in the art, this technical feature cannot be deemed as special.

Election of Species

Claims 1-22 are generic to the following disclosed patentably distinct species: coating compositions, methods of coating a device, methods of using a coated device and vehicles. Here the species require chemically dissimilar polymers and bioactive agents. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record. Applicant is required to make an election for each of the following:

- Formula I, such that all monomers are specifically identified by name and structure
- Formula II, such that all monomers are specifically identified by name and structure

Should invention I, II, III, or IV be elected, then also make an election for the particular bioactive

Art Unit: 1615

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention and species.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention and species.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention and species.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

Art Unit: 1615

inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions or species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit
1615